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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,561	01/30/2002	James E. Dvorsky	VI/99-020	7657

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EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/29/2004

2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,561

Applicant(s)

DVORSKY ET AL.

Examiner

Ruth S Smith

Art Unit

3737

CA

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13, 16-24 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13, 16-24 and 27-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6.7.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Objections

Claims 8,22,28-30 are objected to because of the following informalities: In claim 8, line 2, "least" is misspelled. On line 4, "the imaging energy" lacks antecedent basis. Claim 22 is incomplete in that the claim fails to positively set forth a step of detecting extravasation as set forth in the preamble. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7,8,18,33-34,37,38 are rejected under 35 U.S.C. 102(b) as being anticipated by Uber III et al ('026). Uber III et al disclose a first energy source 144 and a first sensor to measure a signal. The signal will inherently be proportional to the energy transformed, reflected, scattered, or absorbed by a fluid present in the vicinity of the site.

Claims 11,35,36 are rejected under 35 U.S.C. 102(b) as being anticipated by Mine or Monaghan. Mine and Monaghan each disclose an ultrasound source and sensor. The sensor is capable of measuring a signal that inherently is proportional to ultrasound energy reflected by a fluid/contrast agent in the vicinity of the site. The source and sensor do not directly contact the skin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9,10, 16-21,23,24,27,31,32,39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber III et al ('026) in view of Atkins. Uber III et al disclose an x-ray imaging device and a means for detecting radioactive radiation that is sensitive to the amount of contrast agent in a body portion. Uber et al further disclose the use of a power injector for injecting the contrast agent into the patient. Uber III et al disclose monitoring the contrast agent levels in a patient's tissues (see figure 6 for example). Uber III et al does not specifically disclose that the monitoring of the contrast agent is used to detect extravasation, however, Uber III et al disclose that the automated injector control improves the efficiency of the system and exposes the patient to a reduced amount of contrast agent. Atkins discloses a device that detects the presence of extravasation of an injected contrast medium and provides a feedback to an electronically controlled injector. Atkins discloses measuring a baseline signal and comparing a measured signal after the injection to the baseline to determine if extravasation has occurred. Extravasation is well known to be harmful to the patient. Therefore, it would have been obvious to one skilled in the art to have modified Uber III et al such that the detected amounts of contrast agent can be used to monitor the presence of extravasation and the injector is thus controlled based upon these amounts in order to reduce the effects of such contrast agent leakage on the patient.

Claims 12,13 rejected under 35 U.S.C. 103(a) as being unpatentable over Mine or Monaghan in view of Atkins. Mine and Monaghan each disclose an ultrasound source and sensor. The sensor is capable of measuring a signal that inherently is proportional to ultrasound energy reflected by a fluid/contrast agent in the vicinity of the site. Atkins discloses a device that detects the presence of extravasation of an injected contrast medium and provides a feedback to an electronically controlled injector. Atkins discloses measuring a baseline signal and comparing a measured signal after the injection to the baseline to determine if extravasation has occurred. Extravasation is well known to be harmful to the patient. Therefore, it would have been obvious to one skilled in the art to have modified Mine or Monaghan such that the detected amounts of contrast agent can be used to monitor the presence of extravasation and the injector is thus controlled based upon these amounts in order to reduce the effects of such contrast agent leakage on the patient.

Claims 22,28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al ('438) in view of Atkins. Unger et al discloses an MR imaging device and a means for detecting a signal that is sensitive to the amount of contrast agent in a body portion. Unger et al disclose mixing an additive with a contrast agent and injecting the mixture into a patient. The additive affects the measured signal. Atkins discloses a device that detects the presence of extravasation of an injected contrast medium. Atkins discloses measuring a baseline signal and comparing a measured signal after the injection to the baseline to determine if extravasation has occurred. Extravasation is well known to be harmful to the patient. Therefore, it would have been obvious to one skilled in the art to have modified Unger et al such that the detected amounts of contrast agent can be used to monitor the presence of extravasation in order to reduce the effects of such contrast agent leakage on the patient.

Response to Amendment

The declaration filed on October 7, 2003 under 37 CFR 1.131 is sufficient to overcome the Karellas reference.

Response to Arguments

Applicant's arguments with respect to claims 7-13,16-24,27-41 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith
Primary Examiner
Art Unit 3737